AMENDMENTS TO THE CLAIMS

1. (currently amended) A parathyroid hormone (PTH) assay control, comprising a composition having a known concentration of a whole PTH component ~~and~~ mixed with a known concentration of a PTH fragment component, comprising:

a) a whole PTH component having an amino acid sequence set forth in SEQ ID NO:1 (PTH_{1-84}), wherein the N-terminal amino acid residue of the PTH molecule must be intact; and

b) a PTH fragment component having an amino acid sequence set forth in SEQ ID NO:1 (PTH_{1-84}), wherein the N-terminal amino acid residue of the PTH fragment starts at any position spanning position 2 through position 33 of the PTH_{1-84}, the C-terminal amino acid residue of the PTH fragment ends at any position spanning position 35 through position 84 of the PTH_{1-84}; and the PTH fragment has a minimal length of three amino acid residues;

wherein the ratio of the whole PTH component to the PTH fragment component ranges between about 1% to about 99%,

wherein said composition further comprises a protein matrix base,

and wherein said assay control is lyophilized.

2. (original) The PTH assay control of claim 1, wherein the composition comprises a total PTH component having the whole PTH component and the PTH fragment component combined in said protein matrix base at a predetermined ratio.

3. (original) The PTH assay control of claim 1, wherein the whole PTH component and the PTH fragment component comprise chemically synthesized PTH peptides or recombinant protein.

4. (original) The PTH assay control of claim 1, wherein the whole PTH component and the PTH fragment component are obtained from natural sources such as human serum, human plasma, or human parathyroid gland.

5. (original) The PTH assay control of claim 4, wherein the whole PTH component and the PTH fragment component are purified prior to incorporation within the protein matrix.

6-7. (canceled)

8. (original) The PTH assay control of claim 1, wherein the shelf-life comprises a minimum of about 3 months.

9. (canceled)

10. (original) The PTH assay control of claim 1, wherein the ratio of the whole PTH component to the PTH fragment component ranges between about 20% to about 80%.

11. (original) A kit comprising one or more controls of claim 1 and instructions therefore.

12. (original) The kit of claim 11, wherein each of the one or more controls comprises a composition having a different known concentration of the PTH components.

13. (original) A kit comprising one or more controls of claim 2 and instructions therefore.

14. (original) The kit of claim 13, wherein each of the one or more controls comprises a composition having a different ratio of PTH components.

15. (original) The kit of claim 13, wherein each of the one or more controls comprises a composition having a different ratio of the whole PTH component versus the PTH fragment component.

16. (withdrawn) A method to verify the accuracy of a PTH assay, comprising one or more trials of the following:

a) evaluating the control of claim 1 utilizing a PTH assay having a specificity for a PTH component in the control;

b) determining the concentration(s) of the PTH components in the composition utilizing the assay of step a); and

c) comparing the results obtained in step b) with the known concentration(s) of the one or more components in the control or previously obtained values for the control;

wherein the results of step c) are utilized to provide a basis for accepting, rejecting or interpreting PTH assay results obtained through the use of the PTH assay of step a) for non-control samples.

17. (withdrawn) The method of claim 16, further comprising generating a standard deviation of the control results from previous assay trials after one or more trials in order to derive a basis for accepting or rejecting future assay runs.

18. (withdrawn) The method of claim 16, wherein the PTH assay comprises one or more PTH assays, each having a specificity for a different PTH component, or a combination of the PTH components, present in the control.

19. (withdrawn) A method to improve the accuracy of a PTH assay, comprising one or more trials of the following:

a) evaluating the control of claim 2 utilizing a PTH assay having a specificity for a PTH component in the control, whereby each PTH component in the control is evaluated;

b) determining the concentration of each of the PTH components and the ratio of PTH components in the control utilizing the assay of step a); and

c) comparing the results obtained in step b) with the known concentration(s) and predetermined ratio of the components;

wherein the results of step c) are utilized to modify or interpret PTH assay results obtained through the use of the PTH assay of step a) for non-control samples.

20. (withdrawn) The method of claim 19, wherein step a) may comprise evaluating the control by multiple PTH assays having different specificities and the concentration(s) of the one or more components are determined by combining the results of the multiple PTH assays.

21. (withdrawn) A method to verify the accuracy of a combination of PTH assays, comprising one or more trials of the following:

a) evaluating the control of claim 2 utilizing a PTH assay having a specificity for whole PTH and determining the concentration of whole PTH in the control;

b) evaluating the control of claim 2 utilizing a PTH assay that detects whole PTH and PTH fragments and determining the concentration of the whole PTH and PTH fragment components in the control;

c) determining the ratio of whole PTH versus PTH fragments by comparing the evaluation results of steps a) and b);

d) comparing the results obtained in step c) with the predetermined ratio or previously obtained ratio of the control of claim 2;

wherein the results of step d) are utilized to accept, reject or modify or interpret PTH assay results obtained through the use of the PTH assays of steps a) and b) for non-control samples.

22. (withdrawn) The method of claim 21, further comprising generating a standard deviation of the results of step c) after one or more trials.

23. (withdrawn) The method of claim 21, wherein each of the one or more trials entails the evaluation of a different control having a different predetermined ratio.

24. (withdrawn) The method of claim 21, wherein the PTH assay of step a) detects whole PTH having an intact N-terminal portion, and the PTH assay of step b) detects total PTH levels.